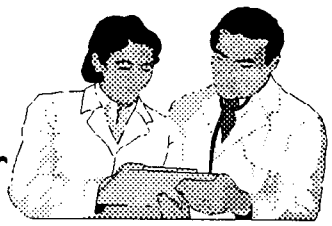
LabLink



Laboratory Information from the Michigan Department of Public Health

Vol. I, No. 3 February 1996

CLIA UPDATE

Frances Pouch Downes, Dr.P.H.

The Public Health Service and the Health Care Financing Administration published the sixth modification of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) on April 24, 1995. The newest CLIA '88 rules with the previous five rules form the framework of the oversight program which regulates patient testing sites and incorporates changes recommended by the CLIA advisory panel since the last rule change in 1993. In addition to changes to CLIA '88, the advisory panel responded to comments.

MODERATELY COMPLEX HDL TESTS

Abbott TDX, Abbott TDX FLX, Abbott Vision Non Whole Blood HDL Procedure, and the BioAutoMed ASCA HDL procedures have been re-categorized from high complexity to moderate complexity.

GROWTH/NO GROWTH

A new test system designation (22167) "Growth/No Growth of Bacteria on Solid Media" was categorized as moderately complex. Final reports for moderately complex bacterial cultures on solid media are limited to "No Growth", "Growth" or "Growth-Referred for Identification or Interpretation". Note that growth of normal flora, contaminants or other non-pathogens cannot be reported as "No Growth". PRESUMPTIVE identification of *N. gonorrhoeae* from urogenital or rectal sites (using selective media, oxidase and Gram stain) and Group A Strep from throat swabs (using selective media, hemolysis and bacitracin) remain categorized as moderately complex.

NEW WAIVED TESTS

Blood glucose monitoring devises FDA approved for home use: Ames Glucometer ENCORE QA Blood Glucose Meter, Ames Glucometer QA Blood Glucose Meter, Hemocue

Spun hematocrit test systems: Separation Technology STI HeamataStat II and Separation Technology STI HemataStat Model C70

Fecal Occult Blood: SmithKline GASTROCCULT

The complexity classification of 2,900 NEW TEST SYSTEMS were categorized as moderate or high.

HIGH COMPLEXITY PERSONNEL REQUIREMENTS REVISED

After September 1, 1997 testing personnel must have at least an associate's degree in laboratory science or medical laboratory technology or the equivalent education and training to qualify as high complexity testing personnel. Until September 1, 1997 high school graduates with adequate training may perform high complexity testing with supervisory oversight. High school graduates or the equivalent who were performing high complexity tests on or before April 24, 1995 may continue testing with supervision even after the September 1, 1997 deadline.

PROVIDER PERFORMED MICROSCOPY

Provider-performed microscopy (PPM) is designated as a subcategory of moderately complex testing, subject to quality control, quality assurance, proficiency testing and patient test management, but not routine inspection. With a PPM certificate physicians (doctors of medicine, osteopathy, and podiatric medicine), dentists, and mid-level practitioners (nurse midwives, nurse practitioners and physician assistants) working under the supervision of a physician may perform a limited number of direct microscopic examinations on patients under his/her care or patients of a group practice of which the physician is a member. A physician must be director of a laboratory with a PPM certificate. Any or all waived tests may also be performed with this certificate.

The intent of this subcategory is to include moderately complex tests which require little or no specimen preparation, the specimen is labile or delay in performing the test would compromise the accuracy of the test. Tests which require specimen staining are not included in the PPM subcategory.

Original PPM tests

- Wet mounts
- KOH preps
- Pinworm exams
- Fern tests (vaginal mucus examination for evidence of ovulation)
- Post-coital direct, qualitative examination of vaginal or cervical mucous

Newly added PPM tests

- Nasal smears for granulocytes
- Fecal leukocyte exams
- Qualitative semen analysis (limited to presence/absence of sperm and detection of motility)
- Urine sediment exams

Note that all tests included in the PPM subcategory may performed by personnel qualified to perform moderately complex tests. As in the case of other moderately complex tests, the laboratory must meet all testing and supervisory personnel requirements and will be inspected.

Haemophilus influenzae in Michigan: Trends and Future Directions

Barbara Robinson-Dunn, Ph.D., ABMM, Chief, Microbiology Section
and
Joel Blostein, Immunization Section

Prior to 1984, *Haemophilus influenzae* was the most common cause of meningitis in children under the age of 6 years. Most of these were due to serotype b and caused an overall mortality of 3-6%. In the last few years, there has been widespread use of a vaccine against *H. influenzae* type b in children beginning at 2 months of age. This has resulted in a dramatic decrease in the incidence of invasive disease due to *H. influenzae.* In Michigan from 1984 through 1994, the reported cases of invasive *H. influenzae* type b disease decreased by 95%.

In 1994, there were 19 cases of invasive *H. influenzae* type b disease of which 10 of the 19 were in children less than 5 years old. Of the 10 cases, 5 had meningeal involvement and 4 of the 10 children had received full or partial immunization. Serotyping was done on only 3 of the 10 isolates and 2 were type b.

This presents a challenge to public health. One of the goals of public health is to eliminate invasive *H. influenzae* disease in children less than 5 years old by 1996. Obviously it is imperative that all children receive the entire immunization series at the appropriate times. We must also have serotype information on all *H. influenzae* isolates causing invasive disease. This information will allow determination of the true preventability of the immunization efforts. We would therefore, like all isolates of *H. influenzae* from invasive disease to be serotyped. If your laboratory has discontinued this service, the Microbiology Section would appreciate receiving these isolates and would be glad to provide this testing. This may help lead to a further reduction in a dreaded and devastating but preventable childhood illness.

Michigan Department of Public Health
Influenza Update
December 15 to January 31

Louis Guskey, Ph.D.

The Virology Section has typed 25 isolates of the Influenza virus by the culture method.

CITY	TYPE	NUMBER OF ISOLATES
Flint	Influenza A (H1N1)	1
Grand Rapids	Influenza A (H1N1)	3
Grand Rapids	Influenza A (H3N2)	1
Kalamazoo	Influenza A (H3N2)	1
Lansing	Influenza A (H3N2)	1
Lansing	Influenza A (H1N1)	7
Royal Oak	Influenza A (H1N1)	6
Sturgis	Influenza A (H1N1)	1
Traverse City	Influenza A (H1N1)	3
Traverse City	Influenza A (H3N2)	1

Type H1N1 Taiwan-like and Texas /36/91-like = 84%
Type H3N2 Johannesburg-like = 16%

Beware--THERE IS NO SUCH THING AS THE STOMACH FLU!

Please do not perpetuate the stomach flu myth carried by the media, coaches, and physicians who bend to this popular concept. Influenza is a respiratory virus and in this part of the world, is one of the causative agents of respiratory diseases during the winter months.

Recommendations for the Serologic Diagnosis of Lyme Disease

From MMWR Vol. 44, No. 31

The Second National Conference on Serologic Diagnosis of Lyme disease was held in Dearborn, Michigan in October, 1994. This Conference was co-sponsored by the Association of State and Territorial Public Health Laboratory Directors, the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, the Council of State and Territorial Epidemiologists and the National Committee for Clinical Laboratory Standards. The conference report presented recommendations for serologic test performance and interpretation which included substantial changes in the recommended tests and their interpretation for the serodiagnosis of Lyme disease.

The algorithm of choice was a two-test approach using a sensitive enzyme immunoassay (EIA) or immunofluorescent assay (IFA) followed by a Western immunoblot. This algorithm may be used for diagnosis of active disease or for previous infection. All specimens positive or equivocal by a sensitive EIA or IFA should be tested by a standardized Western immunoblot. Specimens negative by EIA or IFA need not be tested further.

The syndrome was separated into early Lyme disease which is occurs during the first four weeks of illness and late Lyme disease which is illness any time after the first four weeks. When Western immunoblot is used during early Lyme disease, both immunoglobulin M (IgM) and immunoglobulin G (IgG) procedures should be performed. A positive IgM test result alone is not recommended for use in determining active disease in persons with illness of greater than 1 month s duration because the likelihood of a false-positive test result for a current infection is high for these persons. If a patient with suspected early Lyme disease has a negative serology, serologic evidence of infection is best obtained by testing of paired acute- and convalescent-phase serum samples. Serum samples from persons with disseminated or late Lyme disease almost always have a strong IgG response to *Borrelia burgdorferi* antigens.

It was recommended that an IgM immunoblot be considered positive if two of the following three bands are present: 24kDa (OspC), 39 kDa (BmpA) and 41 kDa (Fla). It was also recommended that an IgG immunoblot be considered positive if five of the following 10 bands are present: 18 kDa, 21 kDa (OspC), 28 kDa, 30 kDa, 39 kDa (BmpA), 41 kDa (Fla), 45 kDa, 58 kDa (not GroEL), 66 kDa and 93 kDa. It should be remembered that the 24 kDa and 21 kDa proteins are both considered OspC since the molecular mass varies with the strain of *B. burgdorferi* being tested.

The two-test process has recently been recommended by the FDA Advisory Panel. Therefore, laboratories which do not currently offer this type of testing are invited to submit samples to the Michigan Department of Public Health Laboratory for the two-test method of serologic determination of Lyme disease.

ARSENIC

The Water Analysis Section was somewhat surprised to learn that people are not generally aware that arsenic, a well-known "poison", is a natural constituent of Michigan's groundwater. State standards have been formally established with a maximum limit for arsenic content of 50 parts per billion (ppb) for regulated public water supplies. This very low level of arsenic, i.e. less than one ten thousandth of a percent, is thought to have about a ten-fold safety factor with little evidence of arsenic toxicity for drinking water content below 400 ppb. Previous tests suggest that the great majority of Michigan public and residential water supplies do not approach even this level, although perhaps 1% of systems are in the range of 50-70 ppb.

A statistical correlation between cancer occurrence and the level of arsenic in drinking water has been recently reported. This work has not been confirmed, but an evaluation of the effects of lowering the arsenic standard has been done. In order to comply with this change, the Water Analysis Section implemented a new method for arsenic analysis, Metals Hydride Generation by Atomic Absorption Spectrometry (*Standard Methods for the Examination of Water and Wastewater*, 18th Edition, 1992, Section 3114). The MDL (method detection limit) was lowered from 5 ppb using graphite furnace analysis to 1 ppb using hydride generation. The hydride generation method converts arsenic to its hydride with sodium borohydride reagent and then is aspirated into an atomic absorption atomizer in order to determine concentration. Although the new method is more costly, it lowers the detection limit as needed for proposed new standard levels, which have been suggested as low as 3 ppb. More practical proposals to lower limits to 10-20 ppb could require additional treatment for 10-20% of all supplies to meet the standards.

On January 8, 1996, the Detroit Free Press printed an article about an Oakland County family experiencing rashes, numbness in hands and feet, stomach pains and headaches. Urinanalysis revealed high levels of arsenic. The article indicted the source of illness to be the family's water supply, and referred to a Huron county arsenic test result of 900 ppb (testing source unknown). An unnamed source was also quoted as linking high arsenic levels with the Marshall Sandstone geological formation which extends over a ten county area. Other media outlets picked up the story, warning persons in this area (Huron, Tuscola, Sanilac, Shiawassee, Genesee, Lapeer, Ingham, Livingston, Oakland and Washtenaw counties) to get their wells tested for arsenic.

Fortunately for the laboratory, response to this warning has been limited. Of the estimated thousands of wells in the area only a few hundred have been sampled for arsenic analysis. The Water Analysis Section is, of course, giving this work highest possible priority. We are happy to report that there does not yet appear to be a substantial problem. Reports for the first 251 samples from private wells (received since the recommendation was issued) show only seven results above the limit of 50 ppb with the highest at 78 ppb. This suggests that arsenic levels are somewhat elevated in the counties warned as compared to state averages, however, no findings have yet approached the expected adverse effects level of 400 ppb.

Michigan Sentinel Hospital Laboratory Reported
Penicillin Resistant Study-site[1] Patient Isolates
of *Streptococcus pneumoniae*
Third Quarter, 1995

Region (see map, *figure a*, on p. 5)	Laboratories Reporting	Total Patients with Isolates	Penicillin Resistance[2]	
			Moderate or High Level (percent)	Only High Level (percent)
1	11/11	270	53(20)	17(6)
2	3/ 3	17	3(18)	0(0)
3	2/ 2	34	4(12)	0(0)
4	2/ 2	48	6(12)	2(4)
5 and 6	4/ 4	92	15(16)	14(15)
7	2/ 2	42	4(10)	2(5)
8	2/ 2	52	8(13)	0(0)
10 and 11	3/ 3	33	5(15)	1(3)
12	2/ 2	7	1(14)	0(0)
Total	33/33	618	105(17)	36(6)

[1] Study sites = blood, CSF, deep surgical wound, pleural fluid (fl), peritoneal fl, respiratory specimens or synovial fl.

[2] NCCLS, Performance Standards for Antimicrobial Susceptability Testing, Volume 14, Number 6.

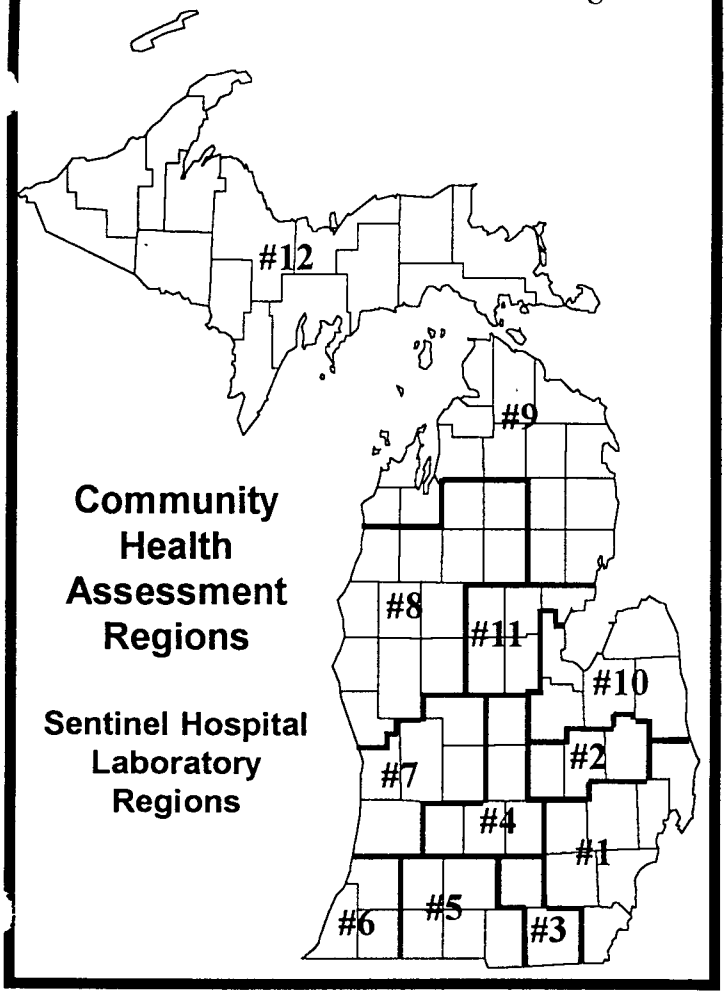
Michigan Sentinel Hospital Laboratory Reported Vancomycin Resistant Study-site[1]
Patient Isolates of *Enterococcus spp.* - Third Quarter, 1995

Region (map, *figure a*, on p. 5)	Laboratories Reporting	Total *Enterococcus*		*Enterococcus faecalis*		*Enterococcus faecium*	
		Patients with Isolates	Resistant[2] (percent)	Patients with Isolates	Resistant[2] (percent)	Patients with Isolates	Resistant[2] (percent)
1	11/11	455	30(7)	306	3(1)	107	26(24)
2	3/3	45	0(0)	42	0(0)	3	0(0)
3	2/2	29	0(0)	29	0(0)	0	-
4	2/2	92	0(0)	38	0(0)	2	0(0)
5 and 6	4/4	92	0(0)	43	0(0)	8	0(0)
7	2/2	30	2(7)	25	0(0)	5	2(40)
8	2/2	48	0(0)	33	0(0)	1	0(0)
9	2/2	66	0(0)	0	-	0	-
10 and 11	3/3	25	0(0)	10	0(0)	1	0(0)
12	2/2	7	1(14)	0	-	0	-
Total	33/33	887	33(4)	526	3(1)	127	28(22)

[1] Study sites = blood, CSF, deep surgical wound, pleural fluid(fl), peritoneal fl, or synovial fl.

[2] NCCLS, Performance Standards for Antimicrobial Susceptability Testing, Volume 14, Number 6.

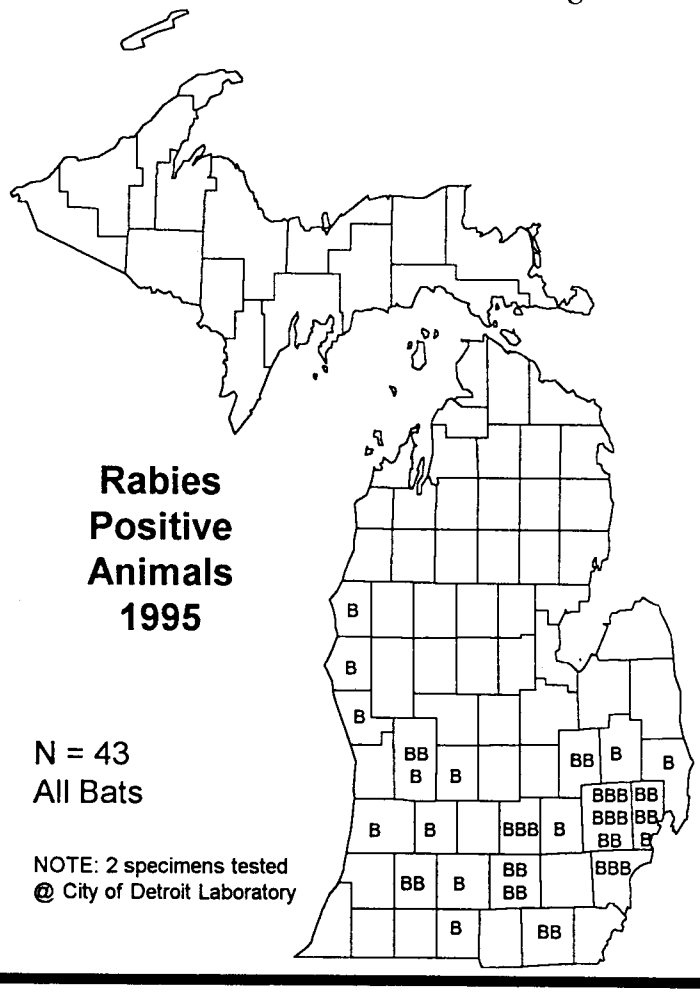
Figure a



Community Health Assessment Regions

Sentinel Hospital Laboratory Regions

Figure b



Rabies Positive Animals 1995

N = 43
All Bats

NOTE: 2 specimens tested @ City of Detroit Laboratory

Specimen Kit Survey

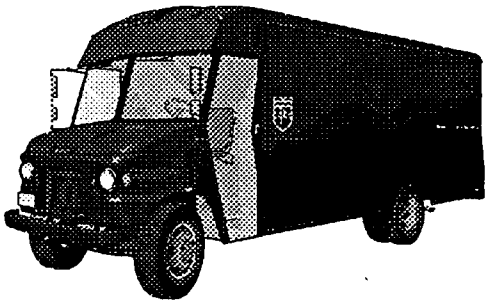
If you have recently ordered supplies (Specimen Collection Units or Water Sample Collection Bottles) from MDPH, please complete the survey below. **We want to hear from you!** Please Fax your survey response to, 517-335-9631,or E-mail (Internet) to DavisS@MDPH.STATE.MI.US, or mail to, Michigan Department of Public Health, Laboratory Services Division, Quality Assurance Section, 3500 Martin Luther King Jr. Blvd., P.O. Box 30035, Lansing, MI 48909.

Your order was:

☐ Satisfactory

- ☐ Filled within one week*
- ☐ Complete

*Did you know - Most orders are shipped within 3 days of reciept. We require twenty-four hours for Lobby Pick Ups. We can track orders that are shipped by UPS within one hour or less.



☐ Unsatisfactory

- ☐ Slow in being filled
  - ☐ More than one week
  - ☐ More than two weeks
  - ☐ Three weeks or more
- ☐ Incomplete
- ☐ Incorrect -, i.e., not what you ordered

How can we improve this service for you?

Advice to the LabLorn...

We are happy to be bringing you the third issue of the LabLink. We hope that you enjoy reading it. Our mission is to bring you information about the Laboratory Division at the Michigan Department of Public Health, and about laboratory testing in the State of Michigan. As you can see in this issue, we have also enlisted the knowledge of the Disease Control Section to bring you information about infectious disease in the state. We hope that if there is any information that you would like to see included in the LabLink, you would call Susan Shiflett at (517) 335-9763.

The Michigan Department of Public Health has a number of professionals willing to lecture, or help you with your inservice training needs. If you need a speaker and would like assistance in locating one, call Susan Shiflett at (517) 335-9763.

We do have a few copies of the National Laboratory Training Network's Resource Guide and Lending Library Catalog available for your use. If you would like a copy, call (517) 335-9763.

As always, we hope that you circulate this information with the people in your laboratory.

If you know someone that should get the LabLink, but they are not, call

(517) 335-9763

Harlan Stiefel Retires

Harlan Stiefel retired from the Michigan Department of Public Health Virology Section on December 29, 1995. His adventure with the department began in September 1953, and continued for forty-two years interrupted only by three years of military service. He has been held in high esteem for accomplishments in syphilis diagnosis, developing a repository for strains of *Legionella spp.*, and standardizing tests for the diagnosis of Lyme's disease. Accolades for his dedication to the health concerns of Michigan residents cannot be overemphasized. Harlan is a long term member of the American Society for Microbiology, frequently presenting abstracts at the annual ASM meetings. He continued to demonstrate dedication to projects even as his health career was winding down. He always maintained a professional attitude and often performed above and beyond the call of duty. His work over the years has gained him the respect and admiration of many colleagues. By his accomplishments, he has made an indelible mark on MDPH and the State of Michigan. We will miss him, and wish him well in his new endeavors.

LabLink is published quarterly by the Michigan Department of Public Health to provide laboratory information to Michigan Health professionals and to the public health community.

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